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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/957,006 | 09/20/2001 | Charles Young | 07039-346001 | 2450 |

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EXAMINER

WINSTON, RANDALL O

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1654 | |

DATE MAILED: 07/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|-------------------------------|-----------------------|
| Application No. 09/957,006 | Applicant(s) Young |
| Examiner Randall Winston | Art Unit 1654 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 1-19 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2, drawn to a method of monitoring the proliferation of cultured prostate cancer cells in the presence of perillyl alcohol (POH) comprising the steps of contacting said prostate cancer cells with POH or derivative thereof; and determining the transactivating ability of an androgen receptor wherein a decrease in the transactivating ability of said androgen receptor is indicative of an inhibitory effect by POH on the proliferation of said prostate cancer cells, classified in class 435, subclass 7.23, for example.
 - II. Claims 3-11, drawn to a method of treating an individual with prostate cancer (i.e. BPH) or at risk of developing prostate cancer or reducing the risk of recurrence of prostate cancer comprising the steps of administering a dose of POH or a derivative thereof to said individual effective to inhibit the transactivating ability of an androgen receptor, wherein inhibiting the transactivating ability of said androgen receptor inhibits the proliferation of prostate cancer cells, thereby reducing the risk of recurrence of prostate cancer in said individual, classified in class 514, subclass 729, for example.
 - III. Claims 12-14, drawn to a method of screening for compounds that inhibits the proliferation of prostate cancer cells comprising the steps of contacting prostate cancer cells with a compound, classified in class 435, subclass 4, for example.

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IV. Claims 15-16, drawn to a composition comprising perillyl alcohol or a derivative and one or more compounds etc., classified in class 435, subclass 147, for example.

V. Claims 17, drawn to a composition comprising perillyl alcohol (POH) or a derivative thereof, classified in class 514, subclass 729, for example.

VI. Claims 18-19, drawn to a composition comprising perillyl alcohol (POH) or a derivative thereof and a packaging material, classified in class 435, subclass 810, for example.

2. The inventive groups above are directed to different inventions which are not connected in design, operation, and/or effect. These claimed methods (Inventions I-III, methods are distinguishable, each from the other, because they are three different methods. The three methods' preambles and/or objectives are either a method of monitoring the proliferation of cultured prostate cancer cells or a method of treating an individual with prostate cancer or a method of screening for compounds that inhibits the proliferation of prostate cancer cells. These different methods utilize different steps and/or approaches to achieve its preamble objective (i.e. Invention I steps are drawn to contacting said prostate cancer cells with POH, Invention II steps are drawn to administering a dose of POH and Invention III steps are drawn to contacting prostate cancers cells with the broad term of a compound (i.e. any compound(?))) and the claimed compositions (Inventions IV-VI are distinguishable, each from the other, because they are three different compositions. The three compositions are either a composition comprising perillyl alcohol and one or more compounds or a composition comprising perillyl alcohol or a

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composition comprising perillyl alcohol and a packaging material) are distinct since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. In addition, one would not have to practice the various methods and/or use the various compositions at the same time to practice just one method alone and/or one composition alone.

3. The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all the above inventions in one application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirements be traversed (37 CFR 1.143).

Any inquiry concerning this communication should be directed to Randall Winston at telephone number (703) 305-0404. The examiner can normally be reached during the hours of 08:30 to 17:00 Eastern.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

Randall O. Winston
Examiner, 1654

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600